IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

TRIGG et al — Atty. Ref.: 47-163

Serial No. Unassigned — Group:

Filed: November 26, 2001 — Examiner:

For: SUSTAINED PEPTIDE-RELEASE FORMULATION

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November 26, 2001

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Please amend this application as follows:

IN THE ABSTRACT

Please cancel the abstract appearing on the first page of the specification and replace by the following new abstract presented on a separate attached to this response.

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ABSTRACT OF THE DISCLOSURE

A pharmaceutical and/or veterinary formulation for sustained release of a peptide agonist or analogue, comprising about 2-15% (w/w) of at least one peptide agonist or analogue other than deslorelin (on an active basis), about 0.5-3.5% (w/w) lecithin and the balance stearin. The formulation preferably comprises a GnRH agonist or analogue and is used for the treatment of various conditions where suppression of sex hormone levels is beneficial, particularly prostate cancer, ovarian and breast cancer, and benign prostatic hyperplasia in dogs.

IN THE SPECIFICATION

Page 10, after line 27, insert –BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail with reference to the accompanying drawings, in which:

Figures 1-8 show the results of implantation into dogs of rods in accordance with the invention in scrotal circumference monitored over time (Treatments 1-8); and

Figures 9-14 show the results of monitoring of plasma testosterone levels in the implanted dogs treated in accordance with Treatments 1-6 described in Figures 1-6, respectively.--

Page 4, line 13, delete "Disclosure" and replace by --Description--.

IN THE CLAIMS

Please cancel all of the claims in this application, namely Claims 1-16, and replace by the following new claims:

17. (New). A pharmaceutical and/or veterinary solid implant formulation comprising about 2-15 % (w/w) of at least one GnRH agonist (on an active basis),

about 0.5-3.5 % (w/w) lecithin and the balance stearin, wherein said GnRH agonist is other than deslorelin.

18. (New). A formulation according to claim 17, comprising about 5-10 % (w/w) of the GnRH agonist (on an active basis), about 0.5-1.5 % (w/w) lecithin and about 89-94 % (w/w) stearin.

19. (New). A formulation according to claim 18, comprising about 5 % (w/w) of the GnRH agonist (on an active basis), 1 % (w/w) lecithin and 94 % (w/w) stearin.

20. (New). A formulation according to claim 18, comprising about 5 % (w/w) of the GnRH agonist (on an active basis), 2 % (w/w) lecithin and 93 % (w/w) stearin.

21. (New). A formulation according to claim 17, wherein the GnRH agonist is a peptide.

22. (New). A formulation according to claim 17, wherein the lecithin and stearin are in a non-crystalline form.

23. (New). A method of treating a disease or condition in an animal for which suppression of sex hormone levels is beneficial, the method comprising administering

to the animal an effective amount of the formulation of claim 17 to ameliorate said disease or condition.

24. (New). A method according to claim 23, wherein the disease or condition is selected from the group consisting of prostate cancer, ovarian and breast cancer, endometriosis, myoma, pre-menstrual tension, uterine fibroids, hirsutism, cyclic auditory dysfunction, porphyria and precocious puberty.

25. (New). A method according to claim 23, wherein the lecithin and stearin are in a non-crystalline form.

26. (New). A method of preventing reproductive function from functioning in an animal, the method comprising administering to the animal the formulation of claim 17.

27. (New). A method according to claim 25, wherein the lecithin and stearin are in a non-crystalline form.

28. (New). A method of treating benign prostatic hyperplasia in an animal, the method comprising administering to the animal the formulation of claim 17 whereby treating the benign prostatic hyperplasia.

29. (New). A method according to claim 28, wherein the animal being treated is a dog.

30. (New). A method according to claim 28, wherein the lecithin and stearin are in a non-crystalline form.

REMARKS

New Claims 17-30 are presented for consideration. In addition, the specification has been amended to improve its form and an Abstract has been presented on a separate sheet. No new matter is entered.

Favorable action on this application is awaited.

Respectfully submitted,

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